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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,354	WELCHER ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-16 are pending and under consideration by the Examiner.

Claim rejections-35 USC § 101, 112, first paragraph

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-16 rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific and substantial asserted utility or a well established utility.

The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of this protein or its significance. Applicant is directed to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday January 5, 2001.

The claims are directed to nucleic acids encoding IL-1 receptor antagonist polypeptides encoded by the nucleotide sequence set forth in SEQ ID NO:1. The invention encompassed by these claims has no apparent or disclosed patentable utility. The instant application has provided a description of the IL-1ra protein encoded by the claimed nucleic acid but does not disclose a specific and substantial biological role for this protein or its significance. There is no biological activity, phenotype, disease or condition that is associated with the claimed nucleic acid. The mere identification of a nucleic acid is not sufficient to impart any particular utility to the claimed nucleic acid without any information on the specific properties of the encoded IL-1ra polypeptide. Since significant further research would be required of a person skilled in the art to

determine how the claimed polypeptides are involved in any activities, the asserted utilities are not substantial. Furthermore, since the asserted utility is not present in a ready-to-use, real-world application, the asserted utility is not substantial. The specification asserts the following utilities for the claimed nucleic acid encoding a IL-1ra polypeptide. (SEQ ID NO:2):

1. to produce variant polypeptides

2. to produce antibodies against the IL-1ra polypeptides

3. to identify molecules, which interact with IL-1ra polypeptides

4. to assay for other modulators of IL-1ra polypeptide activity

5. to use the IL-1ra polypeptides and nucleic acid molecules of the present invention to treat, prevent, ameliorate, and/or detect diseases and disorders.

Each of these asserted utilities shall be addressed in turn.

1. *to produce variant polypeptides*. This asserted utility is not specific or substantial. Since the same assays can be performed with any polypeptide, the asserted utility is not specific to the claimed nucleic acid (SEQ ID NO:1). Also, since the specification does not disclose how the nucleic acid variants, such as molecules with 70% identity to SEQ ID NO:2, and chimeric polypeptides such as Fc fusion polypeptides, can be used, significant further research would be required of a person skilled in the art to determine how to use the claimed IL-1ra variants. Since the asserted utility is not present in a ready-to-use, real-world application, the asserted utility is not substantial.

2. *to produce antibodies against the IL-1ra polypeptides*. This asserted utility is not specific or substantial. Since antibodies can be made to any polypeptide, the asserted utility is not specific to the claimed nucleic acids encoding IL-1ra polypeptides (see Example 4, page 105). Furthermore, the specification does not disclose how anti-IL-1ra antibodies can be used, and therefore further significant research would be required by one skilled in the art to determine how to use the claimed antibodies. Since the asserted utility is not presented in a ready-to-use, real-world application, the asserted utility is not substantial.

3. *to identify molecules, which interact with IL-1ra polypeptides*. This asserted utility is not specific or substantial. The specification alleges that test molecules which interact with IL-1ra can be tested for the ability to increase or decrease IL-1ra polypeptide activity and the measurement of the interaction of the test molecule with IL-1ra polypeptide may be carried out in cell-based binding assays or membrane binding assays (see page 58, last 6 lines). However, the specification does not disclose which activity of IL-1ra would be tested to assay for the increase or decrease in IL-1ra activity by the test compound. Since the asserted utility is not presented in a ready-to-use, real-world application, the asserted utility is not substantial.

4. *to assay for other modulators of IL-1ra polypeptide activity*. This asserted utility is not substantial, and is neither convincing nor specific. The specification asserts that it may be desirable to identify molecules that are modulators, i.e. agonists or antagonists, of the activity of IL-1ra polypeptide using screening methods (see page 57, last 4 lines). However, in the absence of knowledge of the biological significance of the IL-1ra protein, there is no immediately

obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which inhibit its activity or in the identification of receptors thereof (page 7, lines 5-16) is clearly to use it as the object of further research, which has been determined by the courts to be a non-patentable utility. Furthermore, on page 12, lines 17-21, the specification states that the term "biologically active IL-1ra-L polypeptide" refers to at least one activity characteristic of the polypeptide comprising the amino acid sequence of SEQ ID NO:2, however, there is no description of what this activity might be. Since the asserted utility is not presented in a ready-to-use, real-world application, the asserted utility is not substantial.

5. *to use the IL-1ra polypeptides and nucleic acid molecules of the present invention to treat, prevent, ameliorate, and/or detect diseases and disorders.* This asserted utility is not specific or substantial. The specification does not disclose any disorders that are associated with altered IL-1ra levels or functioning. Since the asserted utility is not presented in a ready-to-use, real-world application, the asserted utility is not substantial.

On page 105, Example 5, of the specification, describes a hypothetical example of the expression of the IL-1ra-L polypeptide in transgenic mice and on page 107, Example 6, of the specification, immunohistochemistry of various tissue sections of the transgenic mice is described, without providing any indication whatsoever of the biological activity of the protein encoded by the claimed nucleic acid. Since the instant specification does not disclose a "real world" use for the nucleic acid encoding the IL-1ra-L polypeptide, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 USC § 101 as being useful.

Claim rejections-35 USC § 112, first paragraph-enablement

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, since the claimed invention is not supported by a specific, substantial, and credible asserted utility or a well- established utility for the reasons set forth above, one skilled in the ad clearly would not know how to use the claimed invention.

Claim rejections-35 USC § 112, first paragraph, enablement

4a. Claims 1-16, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The deposit of biological material is considered by the Examiner to be necessary for the enablement of the current invention because the claims require availability of the deposit (see Claims 1-3). Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. When biological material is required to practice an invention, and if it is not so obtainable or available,

the enablement requirements of 35 USC §112, first paragraph, may be satisfied by a deposit of the material. See 37 C.F.R. 1.802. The specification does not provide a repeatable method for obtaining ATCC Deposit No. PTA-1215 and it does not appear to be a readily available material. The ATCC deposit in full compliance with 37 C.F.R. §§ 1.803-1.809 would satisfy the requirements of 35 USC §112, first paragraph.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;(d) a viability statement in accordance with the provisions of 37 C.F.R 1.807; and (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 C.F.R 1.809(d) should be added to the specification. See 37 C.F.R 1.803-1.809 for additional explanation of these requirements.

Claims 4-16 are rejected under 35 U.S.C. 112, first paragraph, insofar as they depend on claims 1-3 for the ATCC number.

Claim rejections-35 USC § 112, first paragraph, written description

4b. Claims 2-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim 4, for example, is a genus claim. Claim 4, sub-part (a) for example, recites a nucleic acid molecule encoding a polypeptide as set forth in SEQ ID NO:2 with "at least one conservative amino acid substitution, wherein the encoded polypeptide is at least 70% identical to the polypeptide as set forth in SEQ ID NO:2", which encompasses nucleic acid variants of the DNA encoding the polypeptide as set forth in SEQ ID NO:2 and no upper limit on the number of conservative amino acid substitutions. Wit respect to claim 4, sub-parts, (c)-(d), the nucleic acid

variants encompass a nucleic acid encoding a protein having one or more amino acid substitutions, and deletions, made to the DNA molecule which encodes the amino acid sequence set forth in SEQ ID NO:2. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. The specification and claims do not place any limit on the number of amino acid substitutions that may be made to the nucleic acid molecule because claim 4 recites "at least one conservative amino acid substitution". Thus, the scope of the claims include numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although the specification states that these types of changes are routinely done in the art (pages 19-20), the specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a nucleic acid encoding a protein set forth in claim 4 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicants were not in possession of the claimed genus of nucleic acid molecules. Similarly, Applicants were not in possession of (1) a nucleic acid encoding C-terminal truncated variants or N-terminal truncated variants of a polypeptide that is at least 70% identical to the polypeptide set forth in SEQ ID NO:2 or (2) a nucleic acid that hybridizes to the complement of the nucleic

acid claimed under hybridization conditions allowing no more than a 21% mismatch between the nucleotide sequences (see claims 2-4).

The claims are drawn to polynuceotides encoding polypeptides having at least 70% sequence identity with a particular disclosed sequence. The claims do not require that the encoded polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polynucleotides that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. As stated above, it is not even clear what region of the protein has the disclosed activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at

page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polynucleotide encoding a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2 but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 5-16 are rejected under 35 U.S.C. 112, first paragraph, insofar as they depend on rejected claims 2-4 for their limitations.

Claim rejections-35 USC § 112, first paragraph, scope of enablement

4c. Claims 2-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding a polypeptide set forth in SEQ ID NO:2, does not reasonably provide enablement for a nucleic acid encoding a polypeptide which is "at least

70% identical to the polypeptide of SEQ ID NO:2" or a nucleic acid molecule that hybridizes to the complement of the nucleotide sequence as set forth in SEQ ID NO:1, under hybridization conditions allowing no more than a 21% mismatch between the nucleotide sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 4, sub-part (a) for example, recites "at least 70% identical" which encompasses nucleic acid variants of the nucleotide sequence set forth in SEQ ID NO:1, which claims are overly broad, since no guidance is provided as to which of the myriad of nucleic acid molecules encoding polypeptide species encompassed by the claims will retain the characteristics of a polypeptide set forth in SEQ ID NO:2. Similarly, claim 4, sub-part (d) for example, encompasses nucleic acid variants of SEQ ID NO:1 which can be generated by conservative or non-conservative changes, deletions, substitutions and insertions of nucleotides in SEQ ID NO:1 and still hybridize to SEQ ID NO:1. Variants of the nucleic acid molecule encoding the IL-1ra-L polypeptide (claim 4(a), 4(c)), can be generated by conservative changes, allelic, splice species or polymorphic variants. However, Applicants have failed to disclose any actual or prophetic examples on expected performance parameters of any of the possible nucleic acid molecules encoding muteins of the IL-1ra-L polypeptide. Moreover, it is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. For example, Mikayama et al. (1993) teaches that the human glycosylation-inhibiting factor (GIF) protein differs from human migration inhibitory factor (MIF) by a single amino acid residue (page 10056, Figure 1). Yet, despite the fact that these proteins are 90% identical at the amino acid level, GIF is unable to carry out the function of MIF,

and MIF does not exhibit GIF bioactivity (page 10059, second column, third paragraph). It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. Voet et al. (1990) teaches that a single Glu to Val substitution in the beta subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic anemia and blood flow blockages (pages 126-128, section 6-3A and page 230, column 2, first paragraph).

There is no guidance provided in the specification as to how one of ordinary skill in the art would generate a nucleic acid sequence encoding a the IL-1ra-L polypeptide other than the one exemplified in the specification. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided

in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

Claims 5-16 are rejected under 35 U.S.C. 112, first paragraph, insofar as they depends on claims 2-4 for their limitations.

Claim rejections-35 USC § 112, first paragraph, scope of enablement

4d. Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell in culture comprising a polynucleotide with the sequence as set forth in SEQ ID NO: 1, does not reasonably provide enablement for *in vivo* transfection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification discloses that the nucleic acids of the current invention can be expressed in a wide variety of host cell types, including cells within a host animal. However, there are no actual or prophetic examples that disclose how to make or use host cells that comprise a DNA sequence as set forth in SEQ ID NO: 1 in an animal. The Examiner cites Eck & Wilson (page 8 1, column 2, second paragraph to page 82, column 1, second paragraph) who report that numerous factors complicate *in vivo* gene expression which have not been shown to be overcome by routine experimentation. These include, the fate of the DNA vector itself (volume distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the

cell, or its secretory fate, once produced. Since the instant disclosure does not address any of the methods necessary to make a host cell in an animal, which comprises the polynucleotide of interest, the claims as written are not enabled. This rejection could be overcome by addition of the limitation wherein the host cells are "isolated".

Claim rejections-35 U.S.C. 112, second paragraph

5. Claims 2-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-4 recite "under hybridization conditions", which are relative and conditional terms and renders the claims indefinite. Furthermore, some nucleic acids, which might hybridize under conditions of specific moderate stringency, for example, would fail to hybridize at all under conditions of high stringency as recited by Applicants on pages 17-18. The metes and bounds of the claims thus cannot be ascertained. Furthermore, the claims are indefinite because they recite the limitation "....that hybridizes to the complement of....under hybridization conditions allowing no more than a 21% mismatch..." it is unclear what the hybridization conditions would be that allow no more than a 21% mismatch to occur. It is suggested that the specific hybridization conditions, for which there is a basis in the instant specification, be recited in the claims.

Claim 4, sub-part (b) recites "C-terminal truncation or N-terminal truncation" which is vague and indefinite because the metes and bounds of these terms are unclear. Is the polypeptide truncated by 10 C-terminal amino acids, 20 or even 40 C-terminal amino acids?

Claim 10 recites "other than the promoter DNA for the native IL-1ra-L polypeptide" which is vague and indefinite because it is unclear which promoter DNA is being excluded and which is being included in the claim.

Claim 16 recites "biologically active fragment..." which is vague and indefinite because it is unclear what the biological activity of the fragment is. Furthermore, this language is vague and indefinite since it encompasses potentially any portion of the heterologous polypeptide including a single amino acid. There is no guidance provided as to what specific sequences the term "biologically active fragment" refers to. Therefore, the metes and bounds of the claim are unclear.

Claims 5-9, 11-15, are rejected as vague and indefinite insofar as they are dependant on claims 1-2 for their limitations.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6a. Claims 2-16 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 9937662 (1999).

WO 9937662 discloses a cDNA encoding a SPOIL protein, said cDNA comprising the nucleotide sequence shown in Figure 1 (also see abstract). The reference also discloses that the cDNA encoding the protein was cloned into an expression vector, pcDNA/Amp vector, which

contains a promoter operably linked to the cDNA insert encoding the SPOIL protein, as shown by the ability of the vector to be expressing a protein (pages 92-93). Host cells were transformed with the cDNA in the vector (page 92, last paragraph). Fusion proteins comprising the SPOIL proteins were also constructed using the cDNA (page 52). The BLASTX computer program was used in determining the percent identity (page 87, lines 22-27). The nucleotide sequence was cloned into a retroviral vector MSCVneo (page 22, last 5 lines; pages 93-94). The cDNA of the reference would be capable of hybridizing to the polynucleotide of SEQ ID NO:1 described in the instant application. Furthermore, a nucleic acid fragment encoding a single amino acid of the reference would meet the limitations of a nucleic acid encoding a fragment of the polypeptide, which has an activity of the polypeptide of SEQ ID NO:2, as recited in claim 16, since no activity has been recited in the claim. Therefore, the cDNA sequence disclosed in the reference meets the limitations of the claimed nucleic acid of claims 2-16.

6b. Claims 2-16 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 855 404 A1 (1998).

EP 0 855 404 discloses a cDNA encoding a IL-1ra beta protein, said cDNA comprising the nucleotide sequence shown in Figure 1 (also see abstract). The reference also discloses that the cDNA encoding the protein was cloned into an expression vector, which contains a promoter operably linked to the cDNA insert encoding the protein, as shown by the ability of the vector to be expressing a protein (pages 7-8). Host cells were transformed with the cDNA in the vector (page 7-8, last paragraph). Fusion polypeptides comprising the protein of the reference were also constructed (page 7, lines 1-8). The BLASTX, BLASTN computer programs were used in determining the percent identity (page 4, lines 34-50). The nucleotide sequence was cloned into a

viral vectors (page 7, lines 52-57). The cDNA of the reference would be capable of hybridizing to the polynucleotide of SEQ ID NO:1 described in the instant application. Furthermore, a nucleic acid fragment encoding a single amino acid of the reference would meet the limitations of a nucleic acid encoding a fragment of the polypeptide, which has an activity of the polypeptide of SEQ ID NO:2, as recited in claim 16, since no activity has been recited in the claim. Therefore, the cDNA sequence disclosed in the reference meets the limitations of the claimed nucleic acid of claims 2-16.

6c. Claims 2-16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,075,222 (1991).

U.S. Patent No. 5,075,222 discloses a cDNA encoding a IL-1ra protein, said cDNA comprising the nucleotide sequence shown in Figure 15 (also see abstract). The reference also discloses that the cDNA encoding the protein was cloned into an expression vector, lambda GT10, which contains a promoter operably linked to the cDNA insert encoding the protein, as shown by the ability of the vector to be expressing a protein (column 27-28). Host cells were transformed with the cDNA in the vector (columns 16-17). The cDNA of the reference would be capable of hybridizing to the polynucleotide of SEQ ID NO:1 described in the instant application. Furthermore, a nucleic acid fragment encoding a single amino acid of the reference would meet the limitations of a nucleic acid encoding a fragment of the polypeptide, which has an activity of the polypeptide of SEQ ID NO:2, as recited in claim 16, since no activity has been recited in the claim. Therefore, the cDNA sequence disclosed in the reference meets the limitations of the claimed nucleic acid of claims 2-16.

Conclusion

No claim is allowed.

Claims 1-16 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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